

Claims

1. A storage stable pharmaceutical preparation comprising oxycodone
5 and naloxone
characterized in that the active compounds are released from the preparation in a sustained, invariant and independent manner.
2. Preparation according to claim 1,
10 **characterized in that** oxycodone and/or naloxone are present in the form of pharmaceutically acceptable and equally active derivatives such as the free base, salts and the like.
3. Preparation according to claim 2,
15 **characterized in that** that oxycodone and/or naloxone are present as their hydrochloride, sulfate, bisulfate, tatrane, nitrate, citrate, bitatrane, phosphate, malate, maleate, hydrobromide, hydroiodide, fumarate or succinate.
4. Preparation according to one of the preceding claims,
20 **characterized in that** oxycodone is present in excess referred to the unit dosage amount of naloxone.
5. Preparation according to one of the preceding claims,
characterized in that Naloxone is present in an amount range of 1 to 50 mg.
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6. Preparation according to one of the preceding claims,
characterized in that oxycodone is present in an amount range of 10 to 150 mg, preferably of 10 to 80 mg.

7. Preparation according to one of the preceding claims,
characterized in that oxycodone and naloxone are present in weight ratio ranges of
maximal 25 : 1, preferably of maximal 20:1, 15:1, especially preferably of 5:1, 4:1,
5 3:1, 2:1 or 1:1.

8. Preparation according to one of the preceding claims,
characterized in that the preparation comprises substantially a non-swella-
ble and non-erosive diffusion matrix.

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9. Preparation according to claim 8,
characterized in that the diffusion matrix comprises at least ethylcellulose and at
least one fatty alcohol as the components that essentially influence the release
behaviour of the active compounds.

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10. Preparation according to claim 8 or claim 9,
characterized in that the preparation does not comprise relevant parts of alkaline
and/or water-swella-ble substances, especially of derivatives of acrylic acid and/or
hydroxyalkyl celluloses.

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11. Preparation according to one of the preceding claims,
characterized in that the preparation contains usual fillers and additional
substances, especially lubricants, flowing agents, plasticizers and the like.

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12. Preparation according to claim 11,
characterized in that it comprises magnesium stearate, calcium stearate and/or
calcium laurate and/or fatty acids, preferably stearic acid as the lubricant.

- 43 -

13. Preparation according to claim 11,
characterized in that it comprises highly-disperse silica, preferably Aerosil®,
Talcum, corn starch, magnesium oxide and magnesium and/or calcium stearate as the
5 flowing agent.

14. A storage stable pharmaceutical preparation comprising oxycodone
and naloxone in a substantially non-swellable diffusion matrix,
characterized in that the matrix is influenced with respect to its substantial release
10 characteristics by ethylcellulose and at least one fatty alcohol and that the preparation
comprises oxycodone and naloxone in a weight ratio of maximal 25:1, preferably
maximal 20:1, 15:1, especially preferably of 5:1, 4:1, 3:1, 2:1 or 1:1.

15. Preparation according to claim 14,
15 **characterized in that** oxycodone and naloxone are present in the form of
pharmaceutically acceptable and equally active derivatives, such as the free-base,
salts, and the like.

16. Preparation according to claim 15,
20 **characterized in that** oxycodone and naloxone are present as hydrochloride, sulfate,
bisulfate, tatrane, nitrate, citrate, bitatrane, phosphate, malate, maleate, hydrobromide,
hydroiodide, fumarate or succinate.

17. Preparation according to one of claims 14 to 16,
25 **characterized in that** oxycodone is present in excess referred to the unit dosage
amount of naloxone.

- 44 -

18. Preparation according to one of claims 14 to 17,
characterized in that naloxone is present in an amount range of 1 to 50 mg.

19. Preparation according to one of claims 14 to 18,
5 **characterized in that** oxycodone is present in an amount range of 10 to 150 mg,
preferably of 10 to 80 mg.

20. Preparation according to one of claims 14 to 19,
characterized in that the preparation comprises a substantially non-swelling and
10 non-erosive diffusion matrix.

21. Preparation according to claim 20,
characterized in that the diffusion matrix comprises at least ethylcellulose and at
least one fatty alcohol as the components that essentially influence the release
15 behaviour of the active compounds.

22. Preparation according to claim 20 or 21,
characterized in that the preparation does not comprise relevant parts of alkaline
and/or water-swelling substances, especially of derivatives of acrylic acid and/or
20 hydroxy alkyl celluloses.

23. Preparation according to one of claims 14 to 22,
characterized in that the fatty alcohols comprise lauryl, myristyl, stearyl,
cetostearyl, ceryl and/or cetyl alcohol, especially preferably stearyl alcohol.
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24. Preparation according to one of claims 14 to 23,
characterized in that the preparation comprises usual fillers and additional
substances, especially lubricants, flowing agents, plasticizers and the like.

- 45 -

25. Preparation according to claim 24,
characterized in that it comprises magnesium stearate, calcium stearate and/or calcium laureat and/or fatty acids, preferably stearic acid as lubricant.

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26. Preparation according to claim 24,
characterized in that it comprises highly dispersed silica, preferably Aerosil®, talcum, corn starch, magnesium oxide, magnesium stearate and/or calcium stearate as flowing agent.

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27. Preparation according to one of the preceding claims,
characterized in that commercially available polymer mixtures which comprise ethylcellulose, preferably Surelease® E-7-7050 are used instead of ethylcellulose.

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28. Preparation according to one of the preceding claims,
characterized in that the preparation has been formulated for oral, nasal, rectal application or for application by inhalation.

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29. Preparation according to one of the preceding claims,
characterized in that the preparation is a tablet, pill, capsule, granule and/or powder.

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30. Preparation according to one of the preceding claims,
characterized in that the preparation or precursors thereof are produced by build-up and/or break-down granulation.

- 46 -

31. Preparation according to one of claims 1 to 29,
characterized in that the preparation or precursors thereof are produced by
extrusion.

- 5 32. Preparation according to one of the preceding claims,
characterized in that the preparation can be stored over a period of at least 2 years
under standard conditions (60% relative humidity, 25°C) in accordance with
admission guidelines.